



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA-2012-N-1239]

Dental Devices; Reclassification of Temporary Mandibular Condyle Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify temporary mandibular condyle prosthesis, a preamendments class III device, into class II (special controls), and rename the device "temporary mandibular condyle reconstruction plate." FDA is also issuing the special controls guideline entitled "Temporary Mandibular Condyle Reconstruction Plate Class II Special Controls Guideline" that sets forth the special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

I. Background--Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical

Devices Act of 1990 (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250), the Medical Devices Technical Corrections Act (Public Law 108-214), the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The

Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended section 513(e) of the FD&C Act, changing the mechanism for reclassifying a device from rulemaking to an administrative order.

Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This section provides that FDA may, by administrative order, reclassify a device based upon "new information." FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a preamendments device. The term "new information," as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., Holland-Rantos Co. v. United States Department of Health, Education, and Welfare, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); Upjohn v. Finch, 422 F.2d 944 (6th Cir. 1970); Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see Bell, 366 F.2d at 181; Ethicon, Inc. v. FDA, 762 F.Supp. 382, 388-391 (D.D.C. 1991)), or in light of changes in "medical science" (Upjohn, 422 F.2d at 951). Whether data before the Agency are old or new data, the "new information" to support reclassification under section 513(e) must be "valid scientific evidence," as defined in section 513(a)(3) of the FD&C Act and 21 CFR

860.7(c)(2). (See, e.g., General Medical Co. v. FDA, 770 F.2d 214 (D.C. Cir. 1985); Contact Lens Association v. FDA, 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the "valid scientific evidence" upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending premarket approval application (PMA). (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).) Section 520(h)(4) of the FD&C Act, added by FDAMA, provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the Federal Register; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket. FDA published a proposed order to reclassify this device in the Federal Register of February 7, 2013 (78 FR 9010) (the 2013 proposed order). FDA received and has considered one comment on the 2013 proposed order, as discussed in section II of this document. On February 12, 1997, FDA held a meeting of a device classification panel described in section 513(b) of the FD&C Act with respect to temporary mandibular condyle prosthesis (the 1997 Panel), and therefore, has met this requirement under section 513(e)(1) of the FD&C Act. As explained further in section II of the 2013 proposed order, a meeting of a device classification

panel described in section 513(b) of the FD&C Act took place in 1997 to discuss whether temporary mandibular condyle prosthesis should be reclassified or remain in class III, and the 1997 Panel recommended that the device be reclassified into class II because there was sufficient information to establish special controls. FDA is not aware of new information since the 1997 Panel that would provide a basis for a different recommendation or findings.

II. Public Comments in Response to the Proposed Order

In response to the 2013 proposed order to reclassify temporary mandibular condyle prostheses and rename the device temporary mandibular condyle reconstruction plates (TMCRPs), FDA received one comment. This comment disagreed with FDA's intent to reclassify these devices from class III to class II. The commenter believes that TMCRPs should be classified as class III (PMA) devices, similar to permanent mandibular condyle prostheses, because reclassification to class II (special controls) would allow TMCRPs to enter the market and be used off-label for permanent use. FDA disagrees with this comment. FDA generally does not regulate the practice of medicine but rather regulates the use of a device as indicated by the party offering the device for interstate commerce. The indications for TMCRP are limited to temporary use by the codified identification. FDA is requiring in the special control guideline for this device (see section IV of this final order) patient labeling for TMCRP devices that clearly indicate that the device "is intended for temporary use (defined as less than 24 months) only. It is not intended to permanently reconstruct the TMJ. It is not intended for permanent treatment of TMJ disorders." FDA recommends that patients discuss the risks and benefits of any treatment with their surgeon, especially if off-label use is involved.

The commenter also states that the special controls are not rigorous enough and that clinical trials are necessary to provide a reasonable assurance of the device's safety and

effectiveness. The commenter suggests that classification to class II (special controls) precludes FDA from requesting clinical data for these devices. FDA disagrees with this comment. FDA believes that the special controls provide a reasonable assurance of safety and effectiveness for TMCRP devices that feature similar technology and indications. The Agency believes it has identified all relevant risks to health (see section V of the 2013 proposed order) and that the mitigation methods described in the associated special controls guideline will be effective in mitigating these risks. These risks and mitigations were based on recommendations from the 1997 Panel and information provided by manufacturers in response to the section 515(i) of the FD&C Act call for information, which included information on preclinical testing and literature reports demonstrating that TMCRPs are effective for temporary reconstruction of the mandible and not associated with complications. FDA is also not precluded from requesting clinical data for TMCRP devices where it is necessary to demonstrate substantial equivalence. See section 513(a)(1)(B) of the FD&C Act.

The commenter also states that the new identification for this device is misleading and that the device should be limited to terminally ill patients who have had a tumor resection procedure. FDA disagrees with these comments. FDA believes the 1997 Panel did not intend to limit the use of TMCRP to terminally ill patients. FDA believes that the identified risks to health associated with TMCRP devices are inclusive for a patient population that has undergone resective surgical procedures, whether the result of a tumor or not, that requires the removal of the mandibular condyle and mandibular bone. Further, FDA believes that the identified special controls mitigate these risks and provide a reasonable assurance of safety and effectiveness in this patient population.

III. The Final Order

Under section 513(e) of the FD&C Act, FDA is adopting its findings as published in the preamble to the 2013 proposed order. FDA is issuing this final order to reclassify temporary mandibular condyle prostheses from class III to class II, rename them temporary mandibular condyle reconstruction plates, and establish special controls by revising part 872 (21 CFR part 872).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the devices. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of TMCRPs, and therefore, this device type is not exempt from premarket notification requirements.

IV. Electronic Access to the Special Controls Guideline

Persons interested in obtaining a copy of the guideline may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidelines and guidance documents is available at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. The guideline is also available at <http://www.regulations.gov>.

To receive "Temporary Mandibular Condyle Reconstruction Plate Class II Special Controls Guideline," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1799 to identify the guidance you are requesting.

V. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final order refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910-0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

VII. Clarifications to Special Controls Guidelines

The special controls guideline reflects changes the Agency is making to clarify its position on the binding nature of special controls. The changes include referring to the document as a "guideline," as that term is used in section 513(a) of the FD&C Act, which the Secretary has developed and disseminated to provide a reasonable assurance of safety and effectiveness for class II devices, and not a "guidance," as that term is used in 21 CFR 10.115. The guideline also clarifies that firms will need either to (1) comply with the particular mitigation measures set forth in the special controls guideline or (2) use alternative mitigation measures, but demonstrate to the Agency's satisfaction that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. Finally, the guideline uses mandatory language to emphasize that firms must comply with special controls to legally market their class

II devices. These revisions do not represent a change in FDA's position about the binding effect of special controls, but rather are intended to address any possible confusion or misunderstanding.

VIII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) of the FD&C Act as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this final order, we are revoking the requirements in § 872.3960 related to the classification of TMCRPs as Class III devices and codifying the reclassification of TMCRPs into Class II.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872--DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 872.3960 is amended by revising paragraph (c) to read as follows:

§ 872.3960 Mandibular condyle prosthesis.

* * * * *

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any mandibular condyle prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a mandibular condyle prosthesis that was in commercial distribution before May 28, 1976. Any other mandibular condyle prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

3. Section 872.4770 is added to subpart E to read as follows:

§ 872.4770 Temporary mandibular condyle reconstruction plate.

(a) Identification. A temporary mandibular condyle reconstruction plate is a device that is intended to stabilize mandibular bone and provide for temporary reconstruction of the mandibular condyle until permanent reconstruction is completed in patients who have undergone resective surgical procedures requiring removal of the mandibular condyle and mandibular bone. This device is not intended for treatment of temporomandibular joint disorders.

(b) Classification. Class II (special controls). The special controls for this device is FDA's guideline entitled "Temporary Mandibular Condyle Reconstruction Plate Class II Special Controls Guideline." See § 872.1(e) for the availability of this guidance document.

Dated: December 23, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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